

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Jerry B. Gin *et al.*
SERIAL NUMBER: 10/772,781 EXAMINER: Lezah ROBERTS
FILING DATE: February 4, 2004 ART UNIT: 1612
FOR: LONG-LASTING, FLAVORED DOSAGE FORMS FOR SUSTAINED
RELEASE OF BENEFICIAL AGENTS WITHIN THE MOUTH

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF JERRY GIN, Ph.D., UNDER 37 C.F.R. §1.132

I, Jerry Gin, hereby declare that:

1. I am a joint inventor of the subject matter claimed in the above-referenced United States patent application.

2. I have been in the health care, pharmaceutical, and biotech fields for over 35 years. I received a Bachelor of Science in Chemistry from the University of Arizona and a Ph.D. in Biochemistry from the University of California, Berkeley. Early in my career, I directed the international pharmaceutical and diagnostic businesses for Dow Chemical. Thereafter, I was a Director of New Business Development and Strategic Planning for Syva, the diagnostic arm of Syntex Pharmaceuticals. I then co-founded ChemTrak, the developer of the widely available home cholesterol test. In 1993, I co-founded my first drug delivery company, Oculex, which became one of the leading ophthalmic drug delivery companies. As President and CEO of Oculex, I developed the technology for controlled release of drugs to the interior of the eye, specifically to treat macular edema. I currently serve as Chairman of Chakshu Research, also a drug delivery company, and co-founded Bennes, Inc., the assignee of the present patent application, in 2002. I have conducted research at the National Institutes of Health and am certified by the American Association for Clinical Chemistry and the American Society of Clinical Pathologists. I have contributed to numerous publications in clinical chemistry and

biochemistry, and am an inventor on more than 35 patents and applications, primarily in the areas of chemical formulation and drug delivery.

3. I have been requested to again review the subject patent application and the pending claims, the Office Actions of record, including the final Office Action mailed July 10, 2008, the Submission which accompanies this Declaration, and the references cited by the Examiner in the Office Actions: U.S. Patent No. 4,528,125 to Alderman et al. ("Alderman"); and U.S. Patent No. 6,183,775 to Ventouras ("Ventouras").

4. I have been also been asked to provide this declaration in order to assist the Examiner in understanding the fundamental distinctions between the subject matter claimed in the patent application and that disclosed in the two cited patents, as well as describe the commercial success of our solution to a long-felt need in the art.

5. It is my understanding that all claims currently pending have been rejected as being unpatentable over Alderman or Alderman combined with Ventouras, on the grounds that patents render obvious the sustained release dosage form we are claiming.

6. In connection with the present analysis, I have reviewed the subject patent application and the pending claims, the Office Actions of record, including the final Office Action mailed July 10, 2008, the Submission which accompanies this Declaration, and the Alderman and Ventouras patents.

7. I was surprised to find out that the PTO has taken the position that Alderman describes a sustained release dosage form analogous to that which we are claiming. My dosage form is a long-lasting, soft, pliable lozenge composed of a matrix of a water-insoluble hydrophilic polymer such as ethylcellulose and an essential oil (and/or a component thereof) as a flavoring agent, which provides for gradual release of the essential oil in the mouth. Alderman does not describe a sustained release matrix or a method of preparing a sustained release matrix; to confirm this, I performed the experiment described below.

8. Specifically, on January 16, 2009, I carried out experimental work to ascertain whether the method and materials described in Alderman would give rise to a sustained release matrix as set forth in the claims of my patent application referenced above. Based upon my reading of the Office Actions, it is my understanding that the PTO has specifically asserted that

Alderman discloses a method in which an essential oil is diffused into ethylcellulose particles and thereby forms a matrix as we have been claiming.

9. In designing my experiment, I wanted to prepare composition using the specific teaching in the Alderman patent that I viewed as "closest" to my own invention. Therefore, I selected the description in Example 1 of Alderman, in which a product intended for administration to the mouth is prepared using ethylcellulose and an essential oil.

10. Accordingly, following the procedure of that example, I combined 11.25 g of ethylcellulose (Ethylcellulose NF Premium, viscosity 45, Lot PH21013T01, CAS No. 009004-57-3; Dow Chemical) with 35 ml deionized water to prepare the 30% solids dispersion containing 75 wt.% ethylcellulose that Alderman starts with. The combination of the two resulted in two layers. I added 3.75 g oleic acid, at which point, the ethylcellulose separated out. The remaining solution had a pH of about 4. I added about 0.5 ml of ammonium hydroxide to bring the pH into the 9-10 range, as described by Alderman. I then added 12.5 g lemon oil. I heated the mixture to 70 degrees C, and stirred at that temperature for 10 minutes. At this point, the mixture had become an extremely viscous, lumpy fluid. I poured the fluid into 4 watchglasses, since my claimed product is a lozenge, not a film. I placed these in an oven to dry at 140 degrees F, as described by Alderman. After 24 hours, the mixture was still not dry. I took 2 of the watchglasses out to air dry, and left the 2 other watchglasses in the oven. After all 4 samples were dry, I observed them carefully. In each case, the mixture had become crisp and hard. I tasted the mixture, and there was a very faint taste of lemon oil flavor; in terms of texture and feel, the Alderman composition, in my opinion, resembled hard plastic.

11. Therefore, the Alderman product does not resemble my soft, sustained release matrix lozenges. In my opinion, the completely dried Alderman material could be formed into a lozenge only if it were ground up and the particles so provided compressed into a hard tablet. This means that the dried Alderman composition cannot be made into a soft, sustained release matrix as I am claiming; rather, the Alderman composition could only be incorporated as an ingredient in an insoluble tablet.

12. My claimed dosage form, by contrast, is soft and comfortable to retain in the mouth for extended time periods. The commercially available products sold by my company

under the names Dentiva, Salese, NuvoraWhite, and NuvoraBreath! (see Appendix A) have been widely acclaimed in a variety of contexts, including diabetes self-management. In the latter case, reference may be had to the article in Appendix B, entitled "Keeping Your Mouth Squeaky Clean" by Shirley Gutkowski, RDH, BSDH (June 15, 2009). Products using the claimed technology have also been recognized as a "revolutionary new soft lozenge" for individuals suffering from xerostomia, or dry mouth; see, e.g., "Introducing Salese -- A New Soft Lozenge for Dry Mouth Sufferers," in Women's Health Weekly, at www.newsrx.com/newsletters/Womens-Health-Weekly (see Appendix C). Many other such articles and blogs may be found by searching "Nuvora" on Google or another search engine.

12. I believe the reason for our success has to do with the fact that essential oils have been found to be effective anti-bacterial agents and oral lubricants, but, as alluded to in the Gutkowski article (Appendix B), there has not been any way to gradually deliver essential oils to the oral cavity over an extended time period. Hard candies are largely ineffective, as are mouthwashes and toothpastes, because such products are held in the mouth for such a short time. Gutkowski states that Nuvora's products overcome this problem by using materials that can be held in the mouth for a long period while essential oils are slowly released, citing our Salese and Dentiva products.

13. We have achieved commercial success quite quickly. Although we did not begin selling any products using the claimed technology until May of 2008, and we do not yet market the products in retail outlets, our sales were up to over \$30,000 per month in well under one year. I attribute our success to the advantages of the technology as summarized above and as recited in the claims of the pending patent application.

14. It is my opinion as well as the opinion of our customers and reviewers that our claimed technology - and the products that embody that technology - represents a significant and nonobvious advance in the art, and, furthermore, which has utility in numerous fields, as evidenced by the positive reception our products have received in disparate contexts (e.g., diabetes management, treatment of xerostomia, breath freshening, dental hygiene, tooth whitening, etc.).

15. There is no doubt in my mind that the claimed dosage form is truly "revolutionary" insofar as it represents the first instance of a sustained release product that

provides for gradual release of a pleasantly flavored antibacterial agent over an extended time period.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

Date: August 27, 2009

By: 
Declarant: Jerry Gin

APPENDIX A



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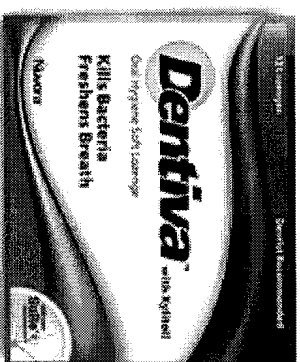
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Ingredients

Dentiva with Xylitol for Oral Hygiene



A Breakthrough in Oral Hygiene

Dentiva oral hygiene lozenges give you fresh breath that lasts for hours. Dentiva doesn't just mask bad breath, it fights bad breath at the source by killing the bacteria that cause it — bacteria that can also cause tooth decay and gum disease. When you can't brush or floss, reach for Dentiva!

Item Number: 4000

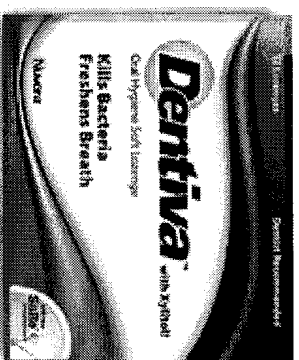
Price: \$5.99

Buy Now

Dentiva with Xylitol for Oral Hygiene (6 Boxes)

A Breakthrough in Oral Hygiene

Dentiva oral hygiene lozenges give you fresh breath that lasts for hours. Dentiva doesn't just mask bad breath, it fights bad breath at the source by killing the bacteria that cause it — bacteria that can also cause tooth decay and gum disease. When you can't brush or floss, reach for Dentiva!



Item Number: 4000-6

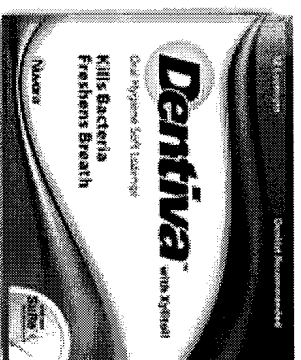
Price: \$35.94

[Buy Now](#)

Dentiiva with Xylitol for Oral Hygiene (12 Boxes)

A Breakthrough in Oral Hygiene

Dentiiva oral hygiene lozenges give you fresh breath that lasts for hours. Dentiiva doesn't just mask bad breath, it fights bad breath at the source by killing the bacteria that cause it — bacteria that can also cause tooth decay and gum disease. When you can't brush or floss, reach for Dentiiva!



Item Number: 4000-12

Price: \$69.99

[Buy Now](#)

Ingredients

Ethyl Cellulose Polymer,
Peppermint Oil,
Menthol,
Gum Arabic,

Sucralose,
Xylitol,
Sodium Bicarbonate,
Eucalyptus Oil,
Thymol,
Wintergreen,
Glycerol,
Zinc Gluconate.

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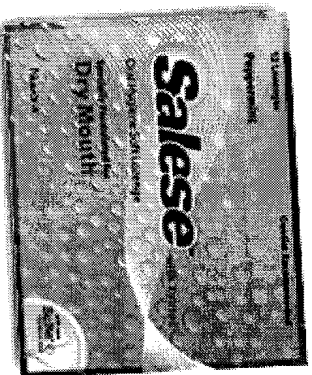
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Ingredients

Salese Peppermint with Xylitol for Dry Mouth Sufferers



A revolutionary oral hygiene lozenge

- 9 out of 10 dry mouth sufferers prefer Salese to other products

- More convenient than sprays or mouthrinses
- Each lozenge lasts one hour or more
- Keeps mouth clean and fresh
- Prevents bad breath and kills bacteria
- Maintains normal pH
- Sugar and alcohol free

Item Number: 4001

Price: \$6.99

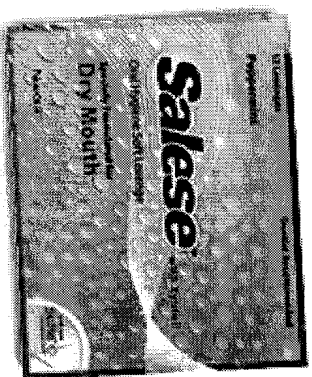
Buy Now

Salese Peppermint with Xylitol for Dry Mouth Sufferers (6 Boxes)

A revolutionary oral hygiene lozenge

- 9 out of 10 dry mouth sufferers prefer Salese to other products

- More convenient than sprays or mouthrinses
- Each lozenge lasts one hour or more
- Keeps mouth clean and fresh



- Prevents bad breath and kills bacteria
- Maintains normal pH
- Sugar and alcohol free

Item Number: 4001-6

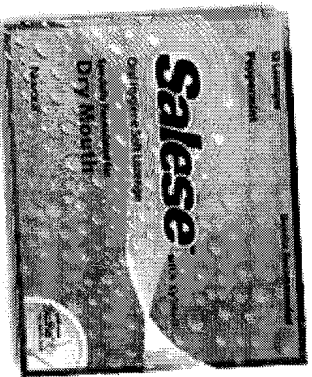
Price: \$41.94

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Salese Peppermint with Xylitol for Dry Mouth Sufferers (12 Boxes)

A revolutionary oral hygiene lozenge

- 9 out of 10 dry mouth sufferers prefer Salese to other products



- More convenient than sprays or mouthrinses
- Each lozenge lasts one hour or more
- Keeps mouth clean and fresh
- Prevents bad breath and kills bacteria
- Maintains normal pH
- Sugar and alcohol free

Item Number: 4001-12

Price: \$79.99

[Buy Now](#)

Ingredients

Xanthan gum: A natural polymer with a "slippery, saliva feel" when it makes contact with the oral mucosa. Salese's slow release technology maintains this moist mouth-feel for prolonged periods.

Essential oils: Bacteria in the mouth combine with muco-polysaccharides to form biofilm. As biofilm continues to grow in a layering fashion, it gets thicker and hardens to form plaque. Salese's essential oils kill bacteria and impedes biofilm. The essential oils in Salese are the same as those used in the leading brand, but without the alcohol that typically causes burning and stinging sensations. So, Salese also tastes better. The essential oils are: peppermint, eucalyptol, thymol and wintergreen.

Xylitol: Salese also contains Xylitol - a powerful inhibitor of bacterial growth. Other mouthwash and spray products offer a short duration of contact with Xylitol, with only a momentary effect on bacteria. Salese delivers Xylitol over a long period of time.

Sodium Bicarbonate: Salese also contains Sodium Bicarbonate which brings the pH balance of the mouth back to neutral and helps prevent demineralization.

Zinc: Zinc neutralizes the sulfur containing compounds that causes bad breath. The basis of the polymer lozenge is cellulose.

Note: For those with very dry mouth conditions it is recommended that Salese be taken with a sip of water to activate the lozenge.

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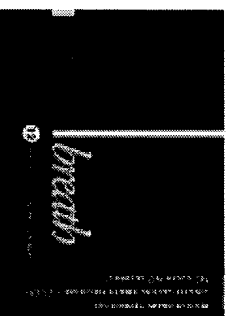
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Ingredients

Nuvora!Breath - When You Care About Your Breath!



The longest lasting fresh breath lozenge!

- Each lozenge lasts one hour or more
- Longer lasting than all other gums, mints, strips, and rinses
- Prevents bad breath and kills bacteria
- Sugar and alcohol free

Item Number: 4002

12 long-lasting soft lozenges

Price: **\$5.99**

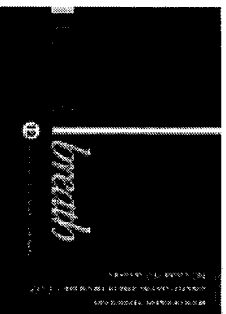
Buy Now

Nuvora!Breath - When You Care About Your Breath! (6 Boxes)

The longest lasting fresh breath lozenge!

- Each lozenge lasts one hour or more
- Longer lasting than all other gums, mints, strips, and rinses
- Prevents bad breath and kills bacteria

- Sugar and alcohol free



Item Number: 4002-6

72 long-lasting soft lozenges

Free shipping

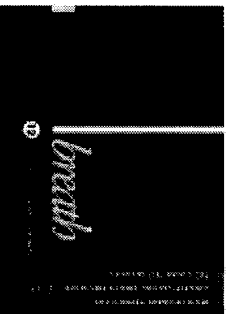
Price: \$35.94

[Buy Now](#)

Nuvora!Breath - When You Care About Your Breath! (12 Boxes)

The longest lasting fresh breath lozenge!

- Each lozenge lasts one hour or more
- Longer lasting than all other gums, mints, strips, and rinses
- Prevents bad breath and kills bacteria
- Sugar and alcohol free



Item Number: 4002-12

144 long-lasting soft lozenges

Free shipping plus save 6%

Price: \$69.99

[Buy Now](#)

Ingredients

Ethyl Cellulose Polymer,
Peppermint Oil,
Gum Arabic,
Menthol, Xylitol,
Sucralose,
Sodium Bicarbonate,
Zinc Gluconate,
Spearmint Oil,
Glycerol

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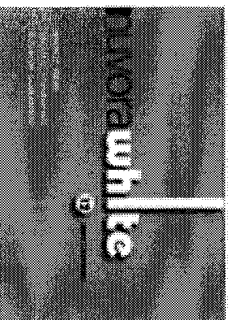
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NuvoraWhite - The Anytime Teeth Whitener!

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More convenient than whitening strips and trays!

- Easy-to-use lozenges with no special application
- Whitens teeth anytime and anywhere
- Freshens breath while it whitens
- Same safe ingredients used by dentists
- 18 day regimen (2 lozenges/day)

Item Number: 4003-3

36 long-lasting soft lozenges

18-day supply

Price: \$59.99

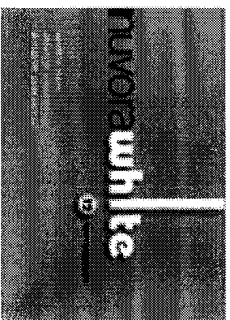
[Buy Now](#)

NuvoraWhite - The Anytime Teeth Whitener! (Whitening plus Touch-up / Maintenance)

More convenient than whitening strips and trays!

- Easy-to-use lozenges with no special application
- Whitens teeth anytime and anywhere
- Freshens breath while it whitens
- Same safe ingredients used by dentists

- 18 day regimen (2 lozenges/day) + Touch-up and Maintenance



Item Number: 4003-6

72 long-lasting soft lozenges

36-day supply

Price: \$109.98

Buy Now

Ingredients

Ethyl Cellulose Polymer,
Peppermint Oil,
Carbamide Peroxide,
Gum Arabic,
Xanthan Gum,
Xylitol, Sucralose,
Zinc Gluconate,
Spearmint Oil

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APPENDIX B

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URL: <http://www.diabetesselfmanagement.com/articles/dental-health/keeping-your-mouth-squeaky-clean/print/>

Keeping Your Mouth Squeaky Clean

Periodontal (gum) disease has been called the sixth complication of diabetes (in addition to eye, kidney, nerve, foot, and cardiovascular complications) because so many people with diabetes have it. Having high blood glucose raises the risk of developing periodontal disease, and periodontal disease tends to raise blood glucose levels. So clearly, making an effort to brush, floss, and have regular dental checkups is important when you have diabetes.

However, sometimes these efforts just don't seem to be enough, and a little more help is needed. This is particularly true when a person has dry mouth, or a lower-than-normal amount of saliva. Normally, saliva protects the teeth and gums by diluting the acids that are excreted by bacteria in the mouth and that are also present in foods and beverages. Saliva additionally contains minerals such as calcium, phosphate, and fluoride that are necessary for rebuilding the teeth and keeping the enamel strong. It also helps you chew and swallow food. When there is not enough saliva to perform these functions, a person's risk of tooth decay, gum disease, and other mouth infections rises.

There are many causes of dry mouth — some avoidable, and some not. Dry mouth is a common side effect of many prescription and nonprescription drugs. It is a symptom or side effect of numerous medical conditions, including diabetes. It can be a side effect of some medical treatments, such as radiation for cancer treatment. It can also be caused by dehydration, smoking or chewing tobacco, or prolonged breathing through your mouth.

While many people are well aware that they have dry mouth, not everyone who has it notices it. However, if you cannot eat a cracker without drinking water, or if your dentist or dental hygienist tells you you have dry mouth, you are at the same heightened risk of tooth decay as someone who is bothered by the dryness.

There are some time-tested home remedies for dry mouth, including sipping water or sugarless drinks throughout the day, chewing sugar-free gum, and using a humidifier at night. It may also help to avoid alcohol, tobacco, and drinks containing caffeine, which can dry out the mouth even more.

In recent years, researchers have developed a number of products to help increase the amount of saliva in the mouth and to counteract the negative effects of not having enough. This article describes some of the newer products to come onto the market, as well as some others still in development. While many are aimed primarily

at consumers with dry mouth, they can all be used by anyone who wishes to step up their home dental care and lower their risk of tooth decay and gum disease.

Xylitol

Sucking on a piece of hard candy can cause you to secrete more saliva and make your mouth feel moister, but sucking on candy sweetened with sugar or most other caloric sweeteners increases the amount of acid in your mouth and raises your risk of tooth decay.

A better option, and one that may actually improve your oral health, is to suck on candy or to chew gum sweetened solely or primarily with xylitol. Xylitol is a type of sugar alcohol that has a minimal effect on blood glucose level. (Sugar alcohols are a type of carbohydrate that are incompletely broken down and absorbed by the body. They contain neither sucrose nor alcohol.) While ingesting too much xylitol can cause diarrhea, regular use of products containing it has been shown to decrease plaque buildup on teeth, which should lower the risk of periodontal disease. Xylitol has also been shown to increase collagen formation, which means it has the potential to strengthen the fibers that hold teeth in place. And a recent study in rats additionally showed that rats that drank water with xylitol in it had increased bone density, making xylitol a potential candidate for the treatment of osteoporosis (weak, porous bones that are prone to fracture).

Studies suggest that ingesting a total of 6–10 grams of xylitol per day — divided into 3–5 smaller doses — lowers the risk of cavities. So far, chewing gum containing xylitol after each meal appears to be the best way to administer xylitol for oral health benefits. Gum must be chewed for about five minutes to get the full dose of xylitol. Other products that are made with xylitol include candies, syrups, mouth sprays, and toothpaste.

Some product labels list the amount of xylitol per serving, while others do not. Look for products with xylitol listed as the only sweetener or as one of the first three ingredients. As the popularity of xylitol rises, some companies are putting tiny amounts into many products just to have it on the list of ingredients. Two brands of gum that are sweetened with 100% xylitol are Spry and B-Fresh, which are widely available in retail health-food and specialty supplement stores. These and other brands are also sold on the Internet.

A different type of product sweetened with 100% xylitol is Xylimelts, which are “domes” of xylitol mixed with vegetable gums that dissolve slowly in the mouth. For convenience, they are formulated to stick to a molar or to gum tissue next to a molar. The domes contain 500 milligrams of xylitol, which is released over an hour or so as they dissolve. The maker of Xylimelts recommends using at least four domes per day after meals and snacks to get maximum benefits. The domes can be purchased over the Internet at www.amazon.com and www.dentaldepot.com and may be available in some retail stores.

The makers of Xylimelts caution that they should not be given to children under five because they pose a choking hazard. Similarly, many experts advise against giving chewing gum to children under four for the same reason. Researchers at the University of Washington in Seattle have been testing whether eating xylitol-sweetened gummy candies several times a day helps to prevent tooth decay in school-age children (grades one through five). However, the American Academy of Pediatrics recommends keeping both hard and sticky candy away from children under four, so these may not be appropriate for younger children, either.

Essential oils

Essential oils — oils extracted from the leaves, stems, flowers, and other parts of plants — have been added to dental products for decades and have been found to be effective at lowering the amount of bacteria in the mouth. Listerine, for example,

contains the essential oil components thymol, eucalyptol, and menthol.

For people with dry mouth, however, products containing essential oils may taste too intense, because there's not enough saliva in their mouths to dilute the product. An obvious solution would be to lower the amount of essential oils in these products to make them tolerable, but because products such as mouthwash and toothpaste are held in the mouth for such a short time, this is not an option. For essential oils to be effective at lowering bacteria levels, they must be used at a high concentration for a short time or a low concentration for a long time.

Some newer products overcome this problem by using materials that can be held in the mouth for a long period while essential oils are slowly released. Two such products from the Nuvora company are Salese and Dentiva. Both are lozenges containing essential oils and xylitol that are designed to take more than an hour to dissolve. Salese is specifically marketed for use by people with dry mouth and contains ingredients to make the mouth feel more slippery. They are currently sold online at <http://store.nuvorainc.com>.

Recaldent

Recaldent is a milk-derived protein that can be used to supply the teeth with calcium and phosphate and to combat acidity in the mouth. Its use may strengthen tooth enamel and decrease tooth sensitivity. Recaldent is found in Trident Xtra Care and Trident White sugar-free chewing gums. (It may be called "calcium casein peptone-calcium phosphate" in the ingredients list found on gum packaging.) Trident Xtra Care also contains xylitol, while Trident White does not.

Recaldent is also the active ingredient in MI Paste, a product currently available only through dental offices. Your dentist or hygienist may apply MI Paste to your teeth during routine cleaning appointments with a polishing cup, a custom tray, or simply a Q-tip or gloved finger. At home, the paste can similarly be applied with a cotton swab or finger. It should be left on the teeth for three to five minutes, after which any excess can be spit out or swallowed, but users are advised not to rinse their mouths with water.

Recaldent does not contain lactose, so it is safe for people who are lactose intolerant, but it should not be used by people with a milk allergy.

Sugar-free chewing gum

Regular sugar-free chewing gums are gaining respect in many dental circles, including the American Dental Association. In 2007, the association gave its Seal of Acceptance to three Wrigley chewing gums, Orbit, Eclipse, and Extra, based on the finding that the physical action of chewing sugar-free gum for 20 minutes after eating stimulates saliva flow, helping to prevent cavities by reducing plaque acids and strengthening teeth. In October 2008, the ADA's Council on Scientific Affairs followed up by giving the ADA Seal to Cadbury products Trident, Dentyne Ice, and Stride sugar-free gums.

Other functional ingredients

In 2008, Wrigley reformulated its Eclipse gums and mints to contain Magnolia bark extract, which is believed to act as an antimicrobial (or "germ killer"). According to the company, the extract kills bacteria associated with bad breath after the gum has been chewed for about five minutes.

Another ingredient that is expected to be added to chewing gum soon is NovaMin, a compound that delivers calcium and phosphate to the teeth for tooth remineralization. NovaMin is currently used in Oravive and Restore brand tooth and dental care products, as well as in some products that are dispensed only by dental offices.

Researchers at the UCLA School of Dentistry have teamed up with the makers of sugar-free candy products to create a lollipop containing licorice root extract. For centuries, people in multiple cultures have chewed licorice root, and the researchers found that a compound in it kills the bacteria responsible for tooth decay. The lollipops are currently being sold under the name Dr. John's Kavidy Kops Lollipops with Glylic, through the Web site www.drjohns.com. Recommendations are to have one lollipop in the morning after breakfast and another before bed for 10 consecutive days. This 10-day regimen should be repeated two to four times per year for continued benefits. (Note that lollipops in general are not considered safe for young children because the sticks could pierce their throats if they were to fall on them.)

Some ordinary beverages with no special ingredients added have also been shown to have positive effects on oral health. Studies on oolong tea show that it slows the growth of bacteria associated with dental decay and also reduces the amount of acid produced by bacteria in the mouth. Ordinary cranberry juice also makes it harder for bacteria to attach to plaque in the mouth. This is beneficial because unlike bacteria that has become part of plaque, unattached bacteria do not produce enough acid to cause problems.

A helping hand

Daily brushing and flossing to break up plaque is still your best weapon against tooth decay and gum disease. But now there are an increasing number of products that can add to your efforts without requiring extra time spent at the bathroom sink. If you're not sure whether a product might be helpful for you, ask your dentist or dental hygienist. But don't be surprised if you heard about it before they did; these days, the innovations are coming so fast and furious it's hard for anyone to keep track of them all.

Shirley Gutkowski has practiced clinical dental hygiene in a number of practices in and around Madison, Wisconsin, since 1986. She was the 2006–2007 President of the Wisconsin Dental Hygienists' Association.

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APPENDIX C

Nuvora**Introducing Salese -- a New Soft Lozenge for Dry Mouth Sufferers**

2008 OCT 30 -- Nuvora has introduced Salese(TM) (formerly Saleve), a revolutionary new soft lozenge for dry mouth sufferers that delivers moisture-retaining and bacteria-fighting ingredients for an hour or longer.

Dry mouth affects at least one in ten adults in the general population. In those over 65 years, the prevalence approaches 25 percent and in institutionalized elders the rates may be as high as 45-50 percent. Almost 40 percent of Florida residents 65+ years have dry mouth.

Dry mouth can cause serious health problems and it is estimated that over 1100 prescription and over-the-counter drugs have the potential to cause dry mouth. These include antacids, decongestants, antihistamines, antihypertensives, antidepressants and diuretics. Dry mouth may also result from Sjogren's syndrome, radiation treatment for head and neck cancers and salivary gland disease.

Traditional treatments for dry mouth have included sugar-free gum or candy, frequent sips of water, oral rinses as well as taking good care of teeth and gums. The ingredients in conventional mouth rinses, gums and mints are flushed away too quickly, limiting their effectiveness.

Now there's a new way to help dry mouth sufferers--Salese(TM), a long-lasting soft lozenge.

The key to Salese's long-lasting properties is Nuvora's patented Sustained Release Technology--SuRe(TM). A unique polymer combined with essential oils, Xylitol and a moisture-retaining ingredient creates an extended contact time in the mouth to fight bacteria and help dry mouth sufferers. Patients simply place Salese in their mouth, without biting or chewing, and let it slowly dissolve for an hour or longer.

Because Salese(TM) is a sustained release product, active ingredients (including Xylitol) are delivered efficiently and continuously in small doses -- up to 1,000 times less than conventional mouthwash. The extended contact with beneficial agents increases both the oral hygiene benefits and the fresh mouth-feel essential to those suffering from Dry Mouth. Patients require less product during the course of a day and derive greater benefits, with no exposure to highly concentrated ingredients. Salese is sugar and alcohol free -- less than one calorie -- and helps maintain a healthy pH balance in the mouth.

It has long been recognized that dental biofilm plays a major role in the etiology of gingivitis, periodontitis, and caries. Although dental biofilm cannot be eradicated, the plaque it forms and its deleterious effects can be controlled with proper and diligent oral hygiene.

Bacteria begin to re-colonize on tooth surfaces immediately after a thorough dental prophylaxis, thereby reinitiating the process of plaque formation. And unfortunately, the active agents contained in short-lived antiseptic mouth rinses, chewing gums and breath mints dissipate or are flushed away quickly. As a consequence of their low residence time in the mouth, they barely affect the biofilm surface. They do not reside in the mouth long enough to allow their active agents to penetrate and dissolve biofilm, whose formidable barrier protects pathogenic and non-pathogenic microorganisms.

Understanding the requirement for long-term delivery of beneficial agents inside the mouth, Nuvora scientists developed the revolutionary SuRe(TM) (Sustained Release) technology that ensures that active agents remain in contact with biofilm for a sufficiently long time (one hour or longer) to materially impede its formation. The end result is long-lasting lozenges that continuously deliver ingredients, over long periods of time, to promote oral and dental health, and freshen breath.

The ingredients used in Nuvora lozenges are generally regarded as safe (GRAS). They kill bacteria, capture the malodors they cause, and impede the formation of biofilm. Evidence shows that lowering bacteria in the mouth promotes cleaner teeth and fresher breath, and reduces the risk of caries, gingivitis, periodontitis, and tooth loss. It also offers the added advantage of improving systemic health as it is now well known that inflammation of gums results in leakage of bacteria and inflammation-inducing compounds into the blood stream, increasing the risk of systemic diseases, including heart disease.

Availability: Consumers can buy Salese(TM) at the company's website www.nuvorainc.com or by calling Nuvora's toll-free number: 1-877-530-9811. Salese(TM) is an over-the-counter product and retailers can contact the company to purchase. Dental offices can purchase sample bags at the company's website or by calling the company.

Keywords: Nuvora, Antidepressant, Head and Neck Cancer, Head and Neck Neoplasms, Oncology, Oral Hygiene, Patents Actions, Salivary Gland Disease, Sjogren Syndrome, Therapy, Treatment.

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